

## **II. Remarks**

### **A. Status of the Claims**

Claims 1, 2 and 4 have been amended without prejudice or admission. Support for “one therapeutic agent consisting of” in claim 1 can be found, e.g., in paragraph [0020] of the original specification. Support for “the substrate overcoated with” in claim 1 can be found, e.g., in paragraph [0025] of the original specification. Support for “a plasticizer” in claim 1 can be found, e.g., in paragraphs [0032] and [0044] of the original specification. Support for “an erosion-promoting agent” in claim 1 can be found, e.g., in paragraph [0064] of the original specification.

New claims 54-60 have been added. Support for new claim 54 can be found, e.g., in paragraph [0064] of the original specification. Support for new claim 55 can be found, e.g., in paragraph [0044] of the original specification. Support for new claim 56 can be found, e.g., in paragraph [0066] of the original specification. Support for new claims 57, 58 and 59 can be found, e.g., in paragraphs [0020] and [0024] of the original specification. Support for new claim 60 can be found, e.g., in paragraph [0021] of the original specification.

Claim 15 has been cancelled without prejudice or admission.

Claims 18-52 were previously cancelled without prejudice or admission.

Claims 1-14, 16, 17 and 53-60 will be pending once the present amendments are entered, with claims 8 and 9 withdrawn from the consideration.

Claims 1-7, 10-14, 16, 17 and 53-60 are encompassed by the elected invention and the elected species.

No new matter has been added by virtue of the present amendments.

**B. Claim Objections**

Claim 19 has been objected to. The Examiner stated that this claim “should be claim 53.”  
Office Action, page 2.

Claim 19 was renumbered as claim 53.

Withdrawal of the objection is respectfully requested.

**C. Claim Rejections- 35 U.S.C. § 102**

Claims 1-7 and 10-17 have been rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,955,104 (“Momberger”).

The rejection is respectfully traversed.

Independent claim 1, the only independent claim included in the present rejection, is directed in part to an opioid antagonist overcoated with two layers- a diffusion barrier coating comprising an anionic polymer and a coating comprising a hydrophobic material and an erosion-promoting agent.

There is no description in Momberger of a dosage form comprising an opioid antagonist overcoated with two layers as recited in claim 1. Applicants respectfully note that the “nonembedding amount of a binder” in Momberger is in the active ingredient layer, and not in a

separate coating. Momberger, column 2, lines 45-51 (“... **the active ingredient layer** ... containing (i) a pharmacologically active particulate ingredient, (ii) a nonembedding amount of a binder for adhering the active ingredient over the inert core, and optionally (iii) a pharmaceutically acceptable, inert adjuvant, such as colloidal silica ...”) (emphasis added).

Momberger does not therefore anticipate the present claims, as it does not teach an opioid antagonist overcoated with two layers as recited in claim 1.

In an effort to advance prosecution of the present application and further differentiate over Momberger, independent claim 1 has been amended to recite “a substrate comprising one therapeutic agent consisting of an opioid antagonist” and “a diffusion barrier coating comprising an anionic polymer and a plasticizer.”

Momberger does not describe any diffusion barrier coatings “comprising an anionic polymer and a plasticizer” as recited in claim 1. In fact, Momberger dissuades from using plasticizers in any coating by stating, e.g., that “[t]he use of plasticizers ... can be most disadvantageous, because these migrate out of the membrane, and this composition change can affect the release of active compound during storage.” Momberger, column 2, lines 12-16.

Momberger also does not teach “a substrate comprising **one** therapeutic agent consisting of an opioid antagonist” as recited in claim 1, because the only mention of opioid antagonist in Momberger is in combination with tilidine. See column 3, line 12 (“tilidine-naloxone”).

In response to the Examiner’s statement on page 4 of the Office Action that “[i]nstant claim 1 does not require that active ingredient particles be coated. Rather, the anionic polymer is to coat the substate” (cf: Office Action, page 4 (emphasis in the original), Applicants respectfully note that amended claim 1 recites that “the substrate [comprising the opioid antagonist is] overcoated with

a diffusion barrier coating.” Because the opioid antagonist is included in the substrate, it is overcoated with a diffusion barrier coating.

In response to the Examiner’s statement that “claim 1 does not require that the substrate be completely coated,” Applicants respectfully note that amended claim 1 recites that “the substrate [is] overcoated with a diffusion barrier coating,” thereby clarifying that the substrate is completely coated.

In response to the Examiner’s statement on page 5 of the Office Action that “Momberger discloses dispersion,” Applicants respectfully note that amended claim 4 recites “the substrate comprises **matrix multiparticulates having** the opioid antagonist dispersed therein,” which is not described in Momberger.

In response to the Examiner’s statement on page 6 of the Office Action that “controlled release and sequestration are inherent properties of hydrophobic materials,” Applicants respectfully submit that this statement is insufficient to establish that “that the allegedly inherent characteristic[s] necessarily flow[] from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

For the foregoing reasons and the reasons articulated in the response filed on September 18, 2008 (herein incorporated by reference), Momberger does not anticipate claim 1 and its dependent claims.

Withdrawal of the anticipation rejection is respectfully requested.

**D. Claim Rejections- 35 U.S.C. § 103**

Claims 1 and 19 have been rejected under 35 U.S.C. § 103(a) over Momberger. The Examiner stated that “[b]ecause both naloxone and naltrexone are opioid antagonists, a person of ordinary skill in the art would have been motivated to add either naloxone or naltrexone.” Office Action, page 4.

The rejection is respectfully traversed.

The only mention of opioid antagonists in Momberger is in combination with tilidine in column 3, line 12, of Momberger (“tilidine-naloxone”).

Momberger does not therefore provide a reason for one skilled in the art to use naloxone by itself, let alone substitute the naloxone with a different opioid antagonist. *In Ex Parte Whallen II, Appeal No. 2007-4423, Decision of Appeal dated July 23, 2008* (“... obviousness cannot be proven merely by showing that the elements of a claimed device were known in a prior art; it must be shown that those of ordinary skill in the art would have had some “apparent reason to combine the known elements in the fashion claimed ... [Similarly,] obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that result in the claimed composition.”).

Furthermore, in an effort to advance prosecution of the present application, independent claim 1 has been amended to recite “a diffusion barrier coating comprising an anionic polymer and a plasticizer.”

Momberger does not teach or suggest “a diffusion barrier coating comprising an anionic polymer and a plasticizer.” In fact, Momberger dissuades from using plasticizers in any coating by stating, e.g., that “[t]he use of plasticizers ... can be most disadvantageous, because these migrate out of the membrane, and this composition change can affect the release of active compound during storage.” Momberger, column 2, lines 12-16.


Momberger does not therefore render claims 1 and 19 obvious.

Withdrawal of the obviousness rejection is respectfully requested.

### **III. CONCLUSION**

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully requested to contact the undersigned by telephone in the event that a telephonic interview will advance the prosecution of the present application.

Respectfully submitted,  
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